DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on May 6, 2010 has been entered.

Withdrawn Rejections

The rejection of claims 1, 3, 4, and 25 under 35 U.S.C. 103(a) as being unpatentable over Klavinskis et al. (J. of Immunol., 1996, 157:2521-2527) and either Ahlers et al. (J. of Immunol., 1997, 158:3947-3958) or Berzofsky et al. (WO 94/26785) has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1, 5-14, 25-35, 70 and 71 under 35 U.S.C. 103(a) as being unpatentable over Klavinskis et al. and either Ahlers et al. (J. of Immunol., 1997, 158:3947-3958) or Berzofsky et al. (WO 94/26785) and further in view of Kiyono et al. (Advanced Drug Delivery Reviews, 18: 23-51) has been withdrawn in view of applicants' amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-14, 25-35, 70 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the reply dated May 6, 2010, applicants' amended claims 1 and 25 to recite that the method of inducing an immune response is performed "without subsequent systemic administration of the composition comprising the chimeric peptide." This is new matter as there is no support in the specification for this limitation.

It is well known in the art that systemic administration means that a drug or other compound goes throughout the body (usually carried in the bloodstream), and includes oral (by mouth), intravenous (injection into the vein, IV), intramuscular (injection into a muscle, IM), intrathecal (into the spinal canal), subcutaneous (beneath the skin, SQ), and rectal administrations. Applicants are directed to the American Academy of Pediatrics report (PEDIATRICS, Vol. 100, No. 1, July 1997) submitted herewith. On page 148 (under Rectal Transmucosal Administration), the report states that "[m]edications may be administered by the rectal mucosal route for systemic effects. . .

Drugs administered low in the rectum are delivered systemically by the inferior and middle rectal veins before passing through the liver." The report also teaches that drug absorption through a mucosal surface is generally efficient because the stratum corneum epidermidis, the major barrier to absorption across the skin, is absent. Mucosal surfaces are usually rich in blood supply, providing the means for rapid drug transport to the systemic circulation and avoiding, in most cases, degradation by first-pass hepatic metabolism. Thus, various methods of administration, such as mucosal, rectal, oral, IV or IM, result in systemic administration of a drug or other compound.

Thus, the limitation "without subsequent systemic administration" means that no other administrations, such as mucosal, rectal, oral, IV or IM, may occur. This is contrary to what the specification teaches. On pages 31 and 32, the specification teaches that administration can be single or multiple. In the case of multiple immunizations, there can, for example, be four weekly administrations, followed (if desired) by a booster administration several months (e.g., two, three, four, six, eight or twelve) or several years (e.g., two, three, four, five, ten, twenty or thirty) thereafter. This means that subsequent systemic administrations via the rectal route were contemplated by applicants. Even some of the examples recite multiple administrations (see, for example, Examples 1-3 where mice were given a dose of antigen on days 0, 7, 14, and 21).

Thus, given the teachings of the specification, applicants did not contemplate a method where only one administration is given and no further systemic administrations via the mucosal, rectal, oral, IV or IM routes were administered.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
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